IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Mary Anne Gross, on behalf of herself and all others similarly situated,	)	**Civil Action No.**
Plaintiff,	)	**CLASS ACTION COMPLAINT**
v.	)	**JURY TRIAL DEMANDED**
AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP,	)	
Defendants.	)	

Plaintiff Mary Anne Gross ("Plaintiff"), individually and on behalf of all others similarly situated, by its undersigned attorneys, files this Class Action Complaint against AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP (hereafter collectively referred to as "Defendants"), upon knowledge as to matters relating to herself and upon information and belief as to all other matters, and alleges as follows:

NATURE OF THE ACTION

1. This class action complaint ("Complaint") alleges violations of federal antitrust and state unfair and deceptive trade practices acts arising from the manufacture and marketing of Toprol-XL® ("Toprol-XL"), a brand name drug. Metoprolol succinate is the generic name for Toprol-XL. Metoprolol succinate is an active chemical compound used for the treatment of angina, hypertension and congestive heart failure.

2. Defendants unlawfully obtained and enforced a monopoly for Toprol-XL and metoprolol succinate through intentional omissions and misrepresentations to the U.S. Patent and Trademark Office ("PTO"). As alleged herein, Defendants obtained several patents, U.S. Patent 5,001,161 (the "'161 patent"), U.S. Patent 5,081,154 (the "'154 patent"), through the use of fraud

and/or inequitable conduct before the PTO and caused them to be listed in the Orange Book (defined below) in a manner that has enabled Defendants to falsely create and extend their market monopoly for Toprol-XL.[1] Defendants protected their patent-enabled monopoly through the filing of sham litigation, irrespective of the fact that they knew or should have known that the patents were unenforceable *ab initio*. As a result of Defendants' unlawful conduct, cheaper generic versions of Toprol-XL were prevented from coming to the United States market, thereby causing injury to Plaintiff and other members of the class.

3. As more fully described below, Defendants maintained patents for metoprolol succinate itself, as well as "sustained release" formulations of metoprolol succinate. Sales of Toprol-XL in 2005 were $1.29 billion, making it the number one drug in revenue for betablockers (a specific type of drug used to treat hypertension), and AstraZeneca's top-selling drug by volume. No generic version of Toprol-XL is currently marketed in the United States because of Defendants' unlawful actions as described herein.

4. As described more fully below, regarding the '161 and '154 patents, Defendants failed to inform the PTO that the '161 and '154 patents were invalid for double patenting over the earlier issued 318 patent. In addition, the '161 patent was not entitled to priority to the 318 patent and the '161 and '154 patents are unenforceable based on the doctrine of inequitable conduct.

5. Moreover, as more fully described below, before and after the patents were issued, Defendants knew that the patents were not enforceable because Defendants and their representatives had knowingly made material omissions and misrepresentations to the PTO in connection with the prosecution of the Patent. As such, Defendants knew or should have known

[1] Also at issue in this case are Defendants' U.S. Patent 4,780,318 (the "'318 patent") and U.S. Patent No. 4,957,745 (the "'745 patent").

that patents '161 and '154, and the corresponding market exclusivity, were illegitimate and unenforceable from their inception.

6. Defendants – through improper manipulation of PTO filings, related submissions to the U.S. Food and Drug Administration ("FDA") and subsequent filing of baseless patent infringement lawsuits – have unlawfully monopolized and/or attempted to monopolize the domestic market for Toprol-XL and its generic bioequivalents.

7. As a result of Defendants' conduct, Plaintiff and the Class (as defined herein) paid for, and continue to purchase, many millions of dollars of Toprol-XL at supra-competitive prices that were significantly higher than what they would have been charged if competing and/or generic versions of Toprol-XL were on the market.

8. At least three manufacturers of generic drugs, KV Pharmaceutical Company ("KV"), Andrx Pharmaceuticals, LLC and Andrx Corporation ("Andrx") and Eon Labs, Inc. ("Eon") (collectively, the "generic manufacturers") filed separate Abbreviated New Drug Applications ("ANDAs") with the FDA requesting approval to market a generic version of Toprol-XL. In their applications, the generic manufacturers asserted that their products are bioequivalents to Toprol-XL and either (i) do not infringe any patent owned by or licensed to Defendants or (ii) that Defendants' underlying '161 and '154 patents for Toprol-XL are invalid.

9. Defendants have engaged in anticompetitive conduct designed to prevent competition from manufacturers of generic bioequivalents to Toprol-XL. Defendants' anticompetitive conduct includes improperly obtaining patents '161 and '154, for the purpose of preventing generic competition. As noted above, Defendants have also filed baseless patent infringements actions against the generic manufacturers, preventing generic versions of Toprol-XL from entering the U.S. market.

10. Unscrupulous strategies like these by brand name companies have not gone unnoticed by federal competition authorities. The Chairman of the Federal Trade Commission ("FTC"), Timothy Muris ("Muris"), for example, in a recent statement before a Congressional Subcommittee, noted that "an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade." Prepared Statement of The FTC Before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives ("FTC Statement"), at 9 (Oct. 9, 2002). Chairman Muris also explained that because "the FDA does not review patents presented for listing in the Orange Book . . . , an NDA filer acting in bad faith...[has the] power to . . . delay[] generic entry and potentially cost[] consumers millions, or even billions, of dollars without valid cause." FTC Statement at 10.

11. Count I of this Complaint is brought by Plaintiff, on behalf of herself and all others similarly situated ("Nationwide End-Payor Class"), seeking injunctive and declaratory relief under Section 16 of the Clayton Act, 15 U.S.C. § 26.

12. Count II of this Complaint alleges monopolization of the market for Toprol-XL in violation of the antitrust laws and/or deceptive trade practices laws of Arizona, California, District of Columbia, Florida, Hawaii, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin (collectively, the "Indirect Purchaser States"), and is brought on behalf of consumers and third-party payors who purchased or paid for Toprol-XL in the Indirect Purchaser States (the "Indirect Purchaser Class") seeking statutory damages, including multiple and treble damages, under applicable state statutory provisions.

13. Count III of this Complaint alleges monopolization of the market for Toprol-XL in violation of the antitrust laws and/or deceptive trade practices laws of the Indirect Purchaser

States and is brought on behalf of the Indirect Purchaser Class seeking injunctive and declaratory relief under applicable state statutory provisions.

14. Count IV is brought by Plaintiff, on behalf of herself and on behalf of the Nationwide End-Payor Class, seeking a constructive trust and disgorgement of the unjust enrichment of Defendants.

JURISDICTION AND VENUE

15. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injuries to Plaintiff and members of the Class resulting from, *inter alia*, Defendants' violations of the federal antitrust laws, for injunctive relief, and for the costs of suit, including reasonable attorneys' fees. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and 15 U.S.C. § 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

16. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) because Defendants reside, transact business, are found, and/or have agents in this district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

INTERSTATE TRADE AND COMMERCE

17. During all or part of the relevant time period:

(a) Defendants manufactured and sold substantial amounts of Toprol-XL in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States;

(b) Defendants transmitted funds, as well as contracts, bills, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Toprol-XL; and

(c) Defendants employed, in furtherance of their monopolization and attempt to monopolize, as alleged herein, the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

18. The illegal monopolization and attempt to monopolize the market for Toprol-XL and its generic bioequivalents alleged herein have substantially affected interstate and foreign commerce.

THE PARTIES

Plaintiff

19. Plaintiff Gross purchased Toprol-XL during the Class Period and, along with the other members of the Class, paid more than she would have absent Defendants' unlawful monopolization and successful attempts to restrict generic competition for Toprol-XL.

Defendants

20. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, with its principal place of business in Södertälje, Sweden.

21. Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware, with its principal place of business in Wilmington, Delaware. Upon information and belief, AstraZeneca LP owns the patents that are the subject of this Complaint.

22. Defendant Aktiebolaget Hässle is a company organized and existing under the laws of Sweden, with its principal place of business in Mölndal, Sweden.

23. Defendants AstraZeneca AB, AstraZeneca LP and Aktiebolaget Hässle are referred to collectively as "Astra" or "Defendants."

RELEVANT MARKETS

24. To the extent applicable to the claims alleged herein, the relevant product market is the market for the manufacture and sale of Toprol-XL, metoprolol succinate, and all generic

bioequivalents rated "AB" by the FDA. The relevant geographic markets are the United States and its territories as a whole (Counts I and IV) and the Indirect Purchaser States (Counts II and III). At all relevant times, up to and including the present, Defendants' market share in the relevant product and geographic markets was 100%.

FACTUAL ALLEGATIONS

25. The manufacture, marketing, distribution, and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at a rate of 14% to 18% per year. In 1997, over $97 billion worth of prescription drugs were dispensed in the United States alone. By 2001, the cost of drugs dispensed in the United States was in the range of $160 billion to $170 billion.

26. To stem the rising cost of prescription drugs, Congress in 1984 amended the Food, Drug, and Cosmetic Act by adding the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. *See* Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)). As more fully explained below, the Hatch-Waxman Amendments were designed to bring cheaper, generic, drugs to market faster. However, in contravention of this expressed goal, Defendants used the Hatch-Waxman Amendments to unlawfully stop generic entry into the market and illegally maintain their Toprol-XL monopoly.

Generic Drugs

27. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which must be approved by the FDA,

have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled.

28. Generic drugs are drugs that the FDA has found to be bioequivalent to brand name drugs, *i.e.*, generic drugs have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

29. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 2% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales. Unless the branded manufacturer lowers prices to meet competition, a branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition.

30. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payers between $8 billion and $10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed: "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."

31. If a generic version of a brand-name drug exists and a prescribing physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing either the branded drug, or the AB-rated generic at a lower price.

32. Once a physician writes a prescription for a brand-name drug such as Toprol-XL, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

33. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy the same chemical substance at much lower prices. Many health insurance companies and employee benefit plans encourage or require substitution of generic drugs for brand-name drugs in order to lower health care costs. Retail pharmacies routinely substitute generic drugs for brand-name drugs whenever possible in order to lower their own costs and the costs of their customers.

Statutory and Regulatory Framework

34. At issue in this case are the Hatch-Waxman Amendments. These amendments were principally designed to streamline the process by which generic drugs are brought to market. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed.Cir.1997). "[T]hrough the Amendments, 'Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.'" *Andrx Pharm., Inc v. Biovail Corp., Int'l.*, 256 F.3d 799 (D.C.Cir. 2001)

(quoting *In re Barr Laboratories, Inc.*, 930 F.2d 72, 76 (D.C.Cir.1991)). *See also Mylan Pharm. v. Shalala*, 81 F. Supp.2d 30, 32 (D.D.C. 2000) ("The stated purpose of the legislation was to 'make available more low cost generic drugs,'" quoting H.R.Rep. No. 98-857, pt. 1, at 14 (1984)).

(i) Pioneer Drugs and The Listing of Patents in the Orange Book

35. In order to market a new drug, the maker of the drug must obtain approval from the FDA. 21 U.S.C. § 355(a). A company seeking FDA approval for a pioneer drug must file a New Drug Application ("NDA"), which, among other things, must include detailed testing data establishing the drug's safety and effectiveness. 21 U.S.C. § 355(b)(1). The NDA must also contain information on each patent that claims the drug or a method of using the drug. 21 U.S.C. § 355(b)(1); (c)(2). More specifically, an NDA filer is required to submit to the FDA:

> [I]nformation on each patent that claims the drug or method of using the drug that is the subject of a new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

21 C.F.R. § 314.53(b) (emphasis added). The FDA publishes the patent information that it receives in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," more commonly known as the "Orange Book."

36. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable regulations. Indeed, the FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . .").

37. Consequently, the Agency's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing. *See aaiPharm, Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002) (recognizing the FDA's "purely ministerial approach to the Orange Book listing process"); *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) ("[The FDA] administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents."); *Purepac Pharm. Co. v. Thompson*, 2002 WL 31840631, *5 (D.D.C. 2002) (recognizing that the duty to ensure that only patents that actually claim approved drugs or methods of use are listed in the Orange Book lies solely with the NDA holders); *Watson Pharm., Inc. v. Henney*, 194 F. Supp. 2d 442, 445 (D. Md. 2001) ("[I]t is paramount to keep in mind that the FDA, in deciding to make an Orange Book listing, is not acting as a patent tribunal. It has no expertise--much less any statutory franchise--to determine matters of substantive patent law. In making its decision to list a patent, therefore, it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to the coverage . . .") (emphasis in original).

38. Moreover, the FDA has no administrative procedures for resolving listing disputes. If a party wishes to dispute a listing, it may notify the FDA of its basis for disagreement. 21 C.F.R. § 314.53(f). In response to such a notification, the FDA will simply request the brand-name company confirm the correctness of the listed patent information. *Id.* Unless the brand-name company voluntarily "withdraws or amends its patent information in response to FDA's request, the FDA will not change the patent information in the list." *Id.*

39. This unilateral ability of brand name companies to cause and maintain the listing of even the most manifestly inappropriate/sustainable patents in the Orange Book creates an opportunity for an unscrupulous brand name manufacturer to wrongfully thwart a generic

competitor from bringing a lower priced generic product to market. That is precisely what happened here.

(ii) How Wrongful Patent Listings are Used to Delay The Entry of Generic Drugs

40. In order to bring low-cost generic drugs to the marketplace more quickly, Congress has provided that generic drugs may be approved through an Abbreviated New Drug Application ("ANDA"), which relies on the FDA's previous determination that the pioneer drug is safe and effective. 21 U.S.C. § 355(j). By using the ANDA procedure, generic manufacturers avoid the costly and timely process of having to replicate and compile the safety and effectiveness data required in the NDA. Moreover, generic manufacturers may use the patented pioneer drug in any way that is necessary to the development of the generic version and the preparation of the ANDA. 35 U.S.C. § 271(e)(1).

41. While Congress wanted to facilitate the entry of generic drugs into the market, at the same time, it also sought to protect the legitimate rights of patent holders that might be infringed by the marketing of generic versions of their patented product. Accordingly, if the owner of the NDA (i.e., the brand name manufacturer) has listed a patent or patents in the Orange Book in relation to the approved brand drug, an ANDA filer is required, as part of its ANDA, to file a specified certification with respect to each such listed patent. This is so even if the listed patent should not have been listed. Because the FDA does not even remotely review the appropriateness or correctness of an Orange Book listing, even if a generic competitor believes that the patent is improperly listed, it must nevertheless file one of the required certifications, or else its ANDA will be deemed incomplete and not approvable. *See* 21 C.F.R. § 314.53(f) (even if generic applicant disputes the appropriateness of an Orange Book listing, if the brand name company refuses to remove the patent voluntarily the generic applicant's ANDA

"must, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.").

42. Specifically, a generic drug maker must certify that the pioneer drug is either: (i) not patented (Paragraph I Certification); (ii) protected by a patent that has expired (Paragraph II Certification); (iii) patented, but setting forth the date the patent will expire (Paragraph III Certification); or (iv) that the pioneer drug's patent is either invalid or will not be infringed by the generic drug (Paragraph IV Certification). 21 U.S.C. § 355(j)(2)(A)(vii). Relevant here is the Paragraph IV Certification, which requires the ANDA applicant to give notice of the filing to both the owner of the patent and to the holder of the NDA for the approved drug. 21 U.S.C. § 355(j)(2)(B)(i)(I).

43. If an ANDA filer submits a Paragraph IV Certification, under the statute, that certification constitutes a "technical act of infringement" which creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

44. The technical act of infringement created under 35 U.S.C.§ 271(e)(2) by the filing of a Paragraph IV Certification is an artificial construct used to create judicial jurisdiction.

45. The mere filing of an infringement action in response to a Paragraph IV Certification, even a meritless infringement action, as here, blocks the entry of a generic competitor, without the brand company ever having to establish likelihood of success on the merits, irreparable harm, balance of hardships or the public good. Indeed, as a practical matter the brand name company automatically protects its monopoly for up to two and a half years

while the infringement action grinds through the court system. This creates a strong incentive for patent holders to file suit against the ANDA filers because there is no disgorgement provisions for profits earned by the patent holder during the thirty-month period of exclusivity if a court determines that the suit is without merit.

46. The first generic company to file an FDA-approved ANDA with a Paragraph IV Certification is granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). Importantly, this 180-day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV Certification. Defendants' misconduct triggered this provision. It thereby reduced the number of competitors, and the extent of price competition.

History of the Toprol-XL Related Patents

47. Defendants manufacture and market "extended release" forms of the drug metoprolol succinate as "Toprol-XL."

Summary

48. Patent '161 is for the "sustained release" form of metoprolol succinate, and Patent '154 is for metoprolol succinate itself.

49. The '161 patent and the '154 patent are invalid for obviousness-type double patenting (non-statutory double patenting) based on claim 8 of the '318 patent.

50. Specifically, the claims in the '161 and '154 patents are a genus of the species described in claim 8 of the '318 patent.

51. In addition, the '161 patent is invalid because: (i) it is not entitled to priority to the '318 patent, and (ii) as anticipated by the publication of a prior Swedish patent application and the related filing of the '745 application (as described below).

The '161 Patent

52. The application for patent '161 was filed on March 25, 1988. It issued on March 19, 1991 and is set to expire on March 19, 2008.

53. The "Abstract" of the '161 patent states that "[t]he present invention relates to metroprolol succinate, a new therapeutically active compound, and pharmaceutical preparations comprising this new compound."

54. The "Description of the Present Invention" states:

> This compound can, in order to be administered orally be treated in accordance with the method proposed in EP-A1-0 040 590. Herein it has been proposed an oral pharmaceutical composition comprising a core containing a therapeutically active compound, which core has been coated with a layer comprising 10 to 85% by weight of an anionic polymer soluble at a pH above 5.5, and 15 to 90% by weight of a water insoluble polymer selected from the group of quarternary ammonium substituted acrylic polymers.
> ...
> When dosing the ready made product a number of discrete, coated particles/granules corresponding to a therapeutical dose unit of the actual therapeutical compound is administered.
> When administering, in order to achieve a steady blood plasma level of the therapeutically active compound provided with a coating according to the present invention can be administered together with some particles/granules which are not coated.

55. The sole claim of the '161 patent is for "[a] sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier." The invention consisted of coated forms of metoprolol succinate that provide for extended release of the drug.

The '154 Patent

56. Defendants applied for the '154 patent on September 28, 1990. It issued on January 14, 1992 and is set to expire on January 14, 2009.

57. The sole claim in the '154 Patent was for the composition of metoprolol succinate itself.

The '318 Patent

58. The'318 patent was applied for on January 10, 1985 and issued on October 25, 1988. It expired on October 25, 2005.[2]

59. The "Abstract" of the '318 patent states that "[t]he present invention relates to a new oral pharmaceutical composition having an improved release of the therapeutically active compound present therein, in the lower part of the gastro-intestinal duct. . . ."

60. The "Background Of The Invention" states as follows:

> There exists an everlasting problem within pharmacy to be able to administer a therapeutically active compound as close as possible to the colon or preferably in the colon, in order to thereby to eliminate the risk of adverse influence on the active compound by the gastric juice, or to prevent irritation of the ventricular mucous membranes, or to obtain a therapeutically effect [sic] in the lower part of the gastrointestinal tract.

61. The "Object Of The Invention" states as follows:

> It has now surprisingly been shown possible to be able to solve the aforesaid problem by the present invention, which is a pharmaceutical composition in unit dosage form characterized by a core comprising a therapeutically active substance in the form of a weak base or a weak acid, on which core there is provided a first, inner layer of a diffusion membrane in the form of ethyl cellulose and/or a copolymer of polyethyl acrylate, methyl methacrylate, and trimethylammonium ethyl methacrylate chloride, and or which inner layer there is provided a second layer of at least one anionic

[2] The application filed claimed priority to Swedish Patent Application No. 84000845, which was filed on January 10, 1984 by Curt H. Appelgren and Eva C. Eskilsson, and published as European Patent Application EP148811 on July 17, 1985.

> polymer and/or fatty acid having a pk suba of 4.5 to 7, preferably 6 to 6.5.

62. The "Detailed Description of the Invention" provided in relevant part:

> By means of the present invention the core is protected against attack by gastric juice after ingestion by means of the outer layer comprising an anionic polymer and/or fatty acid having a pk suba of 4.5 to 7. When this outer layer has been removed by dissolution upon passage of the composition into the small intestine with its higher pH, a slow but controlled release of the therapeutically active compound from the core by diffusion through the diffusion membrane occurs due to the difference in concentrations on each side of said membrane. The release takes thereby place at such a rate that 80-90% of the therapeutically active compound has been released after 7 to 10 hrs, which means that the release can take place in a constant pH independent way, and thereby in a very reproducible way.

63. Claim 8 of the '318 patent (which invalidates the '154 and '161 patents) is set forth below, along with the portions on which it is dependent (claims 6 and 7):

> 6. Oral pharmaceutical composition having an improved release therefrom of a therapeutically active compound therein which is soluble in gastric juice, independent of its solubility, having a core comprising the therapeutically active compound, a first inner layer coating on the core, in the form of a diffusion membrane which is a mixture of ethyl cellulose and a copolymer of polyethyl methacrylate-methyl methacrylate-trimethyl ammonium ethylmethacrylate chloride, in a weight relationship between the monomers or the copolymer of 63 to 65:31.7 to 32.3:2.5 to 5, and a second outer layer coating on the inner layer of at least one anionic polymer having a pk suba of 4.5 to 7.
> 7. Pharmaceutical composition according to claim 6, wherein the therapeutically active compound in the core has a solubility in the pH range of 1 to 8 which exceeds 0.5 to 1 g per 100 ml.
> **8. Pharmaceutical composition according to claim 7, wherein the active compound is quindine sulphate, quindine bisuphate, quindine gluconate, quindine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or furosemide, 5-aminosalycilic acid, propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk suba of 1 to 8**. (emphasis added).

The '745 Patent

64. The '745 patent was issued on September 18, 1990 and set to expire on September 18, 2007. The application that became the '745 patent was filed on February 14, 1989.[3]

The '161 and '154 Patents are Invalid for Double Patenting Over the '318 Patent

65. Courts have recognized the problem of this kind of activity and have fashioned a doctrine of non-statutory double patenting (also known as "obviousness-type" double patenting) to prevent issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant. With non-statutory double patenting, a terminal disclaimer may be filed to restrict the slight variation to the term of the original patent and cure the double patenting rejection.

67. Thus, when patent holders try to wrongfully extend the period of exclusivity by filing claims in a later patent that are not distinct from earlier claims, a court will invalidate the claims that are not patently distinct from an earlier patent because of obviousness-type double patenting. *See Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 189 F. Supp. 2d 377, 381 (E.D. Va. Feb. 25, 2002). A later patent is not patently distinct from an earlier claim if the later claim is obvious or inevitable in light of an earlier claim. If a later claim is anticipated by an earlier claim, there can be no patentable distinction. *Id.*

68. The doctrine of "obviousness-type double patenting" applies, and "requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to

[3] The '745 patent issued from a continuation of a U.S. Patent application that claimed priority to Swedish Patent Application No. 8504721 (the "Swedish Application"), which was filed on October 11, 1985 (naming as inventors Ulf E. Jonsson, John A. Sandberg and John A. Sjogren) and published as UK Patent Application GB2,181,348 on April 23, 1987.

coincide with the term of the first patent to issue." *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F. 3d 955, 957 (Fed. Cir. 2001).

69. Claim 8 discloses a specific application from within the general scope of the '161 patent's claim. Thus, the '161 patent is invalid as a "genus" of claim 8's "species." *See In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001); *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 137, 1383 (Fed. Cir. 2003) (defining a species and genus relationship as one in which the second broader claim is invalid because it is anticipated by, and therefore not patently distinct from, an earlier species claim, making it invalid double patenting).

70. The claim in the '161 patent for "sustained release" formulations of metoprolol succinate is an obvious variant of claim 8. Claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and the claim of the '161 patent is a broad generalized claim to controlled release formulations of metroprolol succinate.

71. The claim in the '154 patent is only for the metoprolol succinate compound, and thus clearly not patentable in light of claim 8. Likewise, the '154 patent, which claims any pharmaceutical compositions containing metroprolol succinate, is a genus of the species in claim 8 of the '318 patent.

The '161 Patent is Invalid as Anticipated by Prior Art Under 35 U.S.C. § 102(b)

72. A claim in a later-filed patent application may claim priority to an earlier-filed patent application under 35 U.S.C. § 120 if the earlier application complies with the written description requirement of paragraph one of 35 U.S.C. § 112, which requires that the specification "contain a written description of the invention, and of the manner and process of making and using it." *See also Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) (to

meet section 112's requirement, "the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the application was filed") (internal citations omitted).

73. The '161 patent was not entitled to priority to the '318 patent application.

74. The specification contained in the '318 patent does not reasonably convey to one of skill in the art that the inventor of the '318 patent possessed the subject matter of the '161 patent at the time the '318 application was filed. In order to be entitled to a priority, the disclosure in the '318 patent would have been required to describe the '161 patent invention, including all of its limitations; this information is absent from the '318 patent.

75. Because the species in the Swedish application was published in July 1985, thus more than one year before the '161 patent application was filed in March 1988, the '161 patent is invalid under 35 U.S.C. § 102(b), which stands for the proposition that a person is entitled to a patent unless the invention was described in a printed publication more than one year before the patent application was filed in the United States.

76. Therefore, because the '745 patent application was filed more than one year before the '161 patent application was filed, the '745 patent constitutes prior art which anticipates the '161 patent and thus renders it invalid for this additional reason as well.

Patents '161 and '154 are Also Invalid Based on Defendants' Inequitable Conduct

77. Patent applicants are required to prosecute patent applications in the PTO with candor, good faith, and honesty. *See Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co. Ltd.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000); *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 818 (1945). Each individual associated with the filing or prosecution of a patent application has a specific duty of candor and good faith in dealing with

the PTO. This includes each inventor named in the application, each attorney or agent who prepares or prosecutes the application, each person who executes a declaration for submission to the PTO during prosecution of the application, and every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the assignee or with anyone to whom there is an obligation to assign the application. The duty of candor and good faith dealing includes a duty to disclose to the PTO all information known to such individuals which is material to the patentability of the claimed invention. (*See* 37 C.F.R. § 1.56). Breach of that duty constitutes inequitable conduct.

78. Inequitable conduct consists of an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false or misleading material information, coupled with an intent to deceive.

79. The actions and omissions of those associated with the filing and/or prosecution of the patents, as set forth below, constitute clear and convincing evidence of (a) intent to deceive the patent office, and (b) inequitable conduct.

80. Prior to the PTO amending its rules in March, 1992, information was deemed material if "a reasonable examiner would substantially likely consider [it] important in deciding whether to allow an application to issue as a patent." *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003) (internal citations omitted). Subsequent to the PTO amending its rules, information is deemed material if it "establishes either 'a prima facie case of unpatentability' or 'refutes, or is inconsistent with a position the applicant takes.'" *Id.* at 1363-64 n.10. However, the new standard established by the PTO was not intended to "constitute a significant substantive break with the previous standard." *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003).

81. Defendants failed to disclose to the PTO numerous material information that would have affected the patentability of the claims regarding Toprol-XL. Specifically the Defendants failed to disclose to the PTO that they were involved in a lengthy contest over the inventorship of metoprolol and also failed to name the correct inventors in their prosecution of the subject patents. In particular, Defendants failed to advise the PTO that:

a) From October 1985 through the late fall of 1988, Astra was engaged in a dispute with one of its competitors, Lejus Medical ("Lejus"), over which company actually invented metoprolol succinate;

b) In 1971, an Astra scientist synthesized metoprolol succinate and the tartrate and sulfate salts of metoprolol. Astra used the salts for commercialization at that time;

c) In the 1980s, Astra formed a research group to develop an extended release formulation of metoprolol. This group included scientists Curt Appelgren and Eva Eskilsson;

d) Appelgren left Astra to form Lejus (a Swedish pharmaceutical research and development company) in December, 1982. He was soon followed by Eskilsson;

e) Lejus filed a patent application for delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate, on January 10, 1984;

f) Thereafter, Lejus and Astra engaged in a contentious dispute over inventorship;

g) Throughout the dispute, Astra was aware that the Lejus publication could be cited as prior art to later applications that concerned metoprolol succinate, threatening Astra's market position; and

h) Appelgren and Eskilsson were improperly named inventors, which, as is evinced by their dispute with Lejus, both untrue and material.

82. The failure to disclose this dispute to the PTO was both material (*i.e.*, there was a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent) and done with an intent to deceive the patent examiner. *See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000) (disputes concerning inventorship are material information that needs to be disclosed) (citing Manual of Patent Examining Procedure § 2001.06(c) and § 2004);

83. Had such information been disclosed to the PTO, that there was a serious ongoing dispute over who invented metoprolol succinate and that the incorrect inventors were listed on the patent applications, this would have undoubtedly affected a reasonable patent examiner's decision to issue a patent.

84. Accordingly, the Patents were and are unenforceable *ab initio*, and Defendants at no time could have reasonably asserted a patent claim on the basis of these inequitably obtained patents. Nor could Defendants reasonably have believed that a claim of infringement of these patents could reasonably be asserted against a proposed generic manufacturer of Toprol-XL.

Defendants' Improper Listing of the Patents

85. Knowing that the patents were obtained by fraud, but faced with generic

competition and the end of their multi-million dollar monopoly, Defendants listed the '161 and '154 patents in the Orange Book. Despite the fact that patents obtained by fraud clearly could not be reasonably listed in the Orange Book or asserted against any generic applicant, Defendants were completely undeterred by the clear listing prohibition imposed by 21 C.F.R. § 314.53(b) because they knew that the FDA would rely entirely upon Defendants' good faith in listing the patents, and would not (and essentially could not) take any action to stop them.

86. Given the unambiguous listing prohibition set forth in 21 C.F.R. § 314.53(b), Defendants plainly and intentionally violated federal law by listing the patents as part of their scheme to block generic Toprol-XL from the market. Unfortunately, it has become common practice in the pharmaceutical industry for brand companies to flout FDA Regulations and list any and every patent they can in the Orange Book so as to force generic manufacturers to file Paragraph IV Certifications. *See Purepac Pharm. Co. v. Thompson*, 2002 WL 31840631 at *14 ("while the regulations tell those parties what they are supposed to do, they do not actually keep non-conforming patents, submitted in violation of the rules, out of the Orange Book... A utopian rule does not automatically create a utopia").

87. Defendants' listing of the patents was objectively and subjectively baseless, and constituted a fraud upon the FDA. The unlawful listing of the patents in the Orange Book was an indispensable predicate act of Defendants' monopoly-preserving scheme, without which Defendants could not have instituted generic entry blocking patent litigation – the mere filing of which, regardless of underlying merit, automatically precluded the FDA from granting approval to the generic applicants for up to thirty months.

88. As a result, Defendants were able to do more than just block all generic applicants from getting FDA approval for over two years. By simply listing their patents and forcing the

generic applicants to file Paragraph IV Certifications in response thereto, Defendants illegally helped themselves to an additional anti-competitive benefit -- namely, the assurance that even when a generic would be finally introduced into the market, for a six month period the number of generic competitors and the extent of price competition would still be substantially diminished, as a result of Defendants' misconduct.

89. It has become fairly established in the marketplace that after the expiration of the first generic's six months of exclusivity, and as more generics enter the market, prices drop significantly, resulting in dramatic savings for consumers. *See* FTC Statement at 18 (recognizing that generic price decreases, and the corresponding benefits to consumers, occur when additional generic competitors enter the market after the expiration of the 180 day exclusivity period).

The Generic Manufacturers' ANDAs

90. The generic manufacturers manufacture generic pharmaceutical products. They submitted ANDA No. to obtain FDA approval for manufacturing and sale of a generic version of oral tablets of metoprolol succinate in July 2002.

91. In conformity with the Hatch-Waxman Act, the generic manufacturers' ANDAs contained a "paragraph IV certification" for the '161 and '154 patents, asserting that each is invalid, unenforceable and/or will not be infringed by their generic products.

Defendants File Baseless Patent Infringement Suits Against the Generic Manufacturers

92. Pursuant to 21 U.S.C. §355(j)(2)(B)(I) and (ii), the generic manufacturers gave written notice to Defendants, via letter, that their ANDAs and the accompanying certifications had been filed with the FDA. In accordance with 21 U.S.C. § 3550)(2)(B)(ii), the notices also set forth the legal and factual bases for their claims that the '161 and '154 patents were either invalid or would not be infringed by their ANDAs.

93. After the receipt of the notices of certification, Defendants brought suit against each of the generic manufacturers for infringement of the '161 and '154 patents (hereinafter referred to as the "Infringement Actions") in the U.S. District Court for the District of Delaware.[4] The filing of the Infringement Actions resulted in the aforementioned 30-month automatic statutory stay of the FDA's authority to grant final marketing approval to the generic manufacturers for their ANDAs for Toprol-XL. The FDA could not grant final marketing approval to the generic manufacturers until they prevailed in the Infringement Actions or until the passage of 30 months, whichever came first.

94. In the Infringement Actions, in addition to claiming that the '161 and '154 patents were invalid, unenforceable and/or would not be infringed by its formulation of Toprol-XL, the generic manufacturers also counterclaimed against Defendants.

95. Despite the knowledge that its Infringement Action was a sham due to their invalid patents and inequitable conduct, Defendants commenced, prosecuted, and maintained the sham Infringement Actions against the generic manufacturers and defended against the counterclaim suits for the improper purpose of maintaining a monopoly in the Relevant Markets, and to conceal by deceit that unlawful interference and monopoly maintenance.

96. Defendants continued to maintain the sham Orange Book listing, the Infringement Action, and their sham defenses of the counterclaim knowingly, intentionally, affirmatively, with the purpose of unlawfully maintaining their monopoly in the Relevant Markets, and with the effect of affirmatively and continuously foreclosing the generic entry of Toprol-XL into the Relevant Markets.

[4] The cases were subsequently transferred to the United States District Court for the Eastern District of Missouri by the Judicial Panel on MultiDistrict Litigation.

97. On January 17, 2006, the United States District Court for the Eastern District of Missouri granted summary judgment to the generic manufacturers.[5] In relevant part, the Court found, by clear and convincing evidence that:

a) the '161 patent and the '154 patent were invalid based on double patenting over the '318 patent;

b) the '161 patent was invalid as anticipated and not entitled to priority to the date of the filing of the '318 patent application;

c) the '161 patent and '154 patent were unenforceable based on Astra's inequitable conduct in the prosecution of these patents, failing to disclose its material dispute with Lejus over the inventorship of metoprolol succinate so as to avoid any potential prior art.

98. Throughout the course of the proceedings before the PTO and for much of the litigation of the Infringement Action, Defendants knowingly, willfully and fraudulently concealed the true facts about their misrepresentations to the PTO in order to wrongfully obtain the patents described herein and to wrongfully prevent and discourage lawful competition with their brand name product Toprol-XL.

99. This fraudulent concealment as described above prevented Plaintiff and the Class from learning the truth about Defendants' illegal conduct which would have allowed earlier actions to be commenced. At all times, Plaintiff was kept in ignorance of the information necessary to know that Defendants had engaged in wrongful conduct or that Plaintiff had been harmed by such conduct.

[5] According to their press releases, Astra intends to appeal this decision, causing further harm to class members.

CLASS ACTION ALLEGATIONS

100. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, specifically Rules 23(b)(2) and 23(b)(3), on behalf of the following class (the "Class"):

> All persons or entities throughout the United States and its territories who purchased and/or paid for Toprol-XL during the period April 5, 2004 to the present ("the Class Period") for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"). For purposes of the Class definition, persons and entities "purchased" Toprol-XL if they paid some or all of the purchase price.

101. Excluded from the Class are Defendants and their respective subsidiaries and affiliates, all governmental entities, agencies, and instrumentalities, and all persons or entities that purchased Toprol-XL for purposes of resale.

102. With respect to Counts II and III, the Class seeks damages as to those persons residing in the Indirect Purchaser States who have paid, in whole or in part, for Toprol-XL during the Class Period (the "Indirect Purchaser State Claims").

103. Plaintiff believes that hundreds of thousands of Americans have purchased Toprol-XL. Thus, members of the Class are numerous and joinder is impracticable. The exact number of persons is currently unknown to Plaintiff, but known to Defendants and/or ascertainable from appropriate discovery.

104. Among the questions of law and fact common to the Class are:

(a) Whether Defendants have unlawfully monopolized or attempted to monopolize the market for Toprol-XL and its generic equivalents;

(b) Whether Defendants possessed and/or unlawfully extended their monopoly power over the market for Toprol-XL and its generic equivalents;

(c) Whether Defendants, through their monopolization and/or attempted monopolization, have caused the prices of Toprol-XL to be maintained at supra-competitive levels;

(d) Whether the Class suffered and continues to suffer antitrust injury; and

(e) Whether Defendants were and continue to be unjustly enriched to the detriment of the Class, entitling Plaintiff and the Class to disgorgement of all monies resulting therefrom.

105. Plaintiff's claims are typical of the Class because Plaintiff and all members of the Class were injured and continue to be injured in the same manner by Defendants' unlawful, anti-competitive and inequitable methods, acts and practices, and wrongful conduct in the conspiracies complained of herein, *i.e.*, they have paid supra-competitive and artificially high prices for Toprol-XL and will continue to be forced to do so until the markets for Toprol-XL and its generic equivalents are competitive and prices reach competitive levels.

106. Plaintiff will fully and adequately protect the interests of all members of the Class. Plaintiff has retained counsel who are experienced in antitrust class action litigation. Plaintiff has no interests which are adverse to, or in conflict with, other members of the Class. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

107. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable and prosecution as a class action will eliminate the possibility of duplicative litigation, while also providing redress for claims which would otherwise be too small to support the expense of individual, complex litigation.

Defendants have acted or refused to act, as alleged herein, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief and/or corresponding declaratory relief with respect to the Class as a whole.

COUNT I

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

108. Plaintiff repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

109. Defendants' filing of obviously invalid patents violates § 2 of the Sherman Act.

110. The intended effect of these baseless patent filings was to delay the introduction of generic formulations of Toprol-XL into the market.

111. As described above, Defendants knowingly and willfully engaged in a course of conduct designated to improperly obtain and extend their monopoly power in the market for a generic of Toprol-XL. This course of conduct included, *inter alia*, the following acts: (i) the intentional omission of material facts from the PTO; (ii) the prosecution of baseless, sham patent litigation against generic competitors; and (iii) maintaining sham defenses to the counterclaim by the generic manufacturers. The result of Defendants' unlawful conduct has been to obtain and extend their monopoly in the relevant markets for Toprol-XL and its bioequivalents.

112. Defendants' Infringement Action constitutes sham litigation, in that the suit was objectively baseless in that Defendants' motivation in bringing the actions was to directly interfere with the ability of the generic manufacturers, as well as other generic competitors, to market less expensive generic versions of Toprol-XL that would compete with the brand-name product.

113. Plaintiff and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Toprol-XL, and paying higher prices for metoprolol succinate products than they would have paid in the absence of the antitrust violation. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

114. Plaintiff and the Class are entitled to a declaration that Defendants' monopolization and attempts to monopolize the market for Toprol-XL and its generic equivalents are in violation § 2 of the Sherman Act.

115. Plaintiff and the Class are entitled to an injunction pursuant to § 16 of the Clayton Act enjoining Defendants' continued monopolistic practices.

116. Plaintiff and the Class have no adequate remedy at law.

COUNT II

FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

117. Plaintiff repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

118. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, et seq., the

Arizona Consumer Fraud Act, Ariz. Rev, Stat §§ 44-1521, et seq., and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, et seq., and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, et seq.;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, et seq.;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542,15, et seq., and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat, Ann. §§ 501.201, et seq.;

e. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statues §§ 480-2, 480-3, and 480-4.

f. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann §§ 50-101, et seq.,and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, et seq.;

g. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, et seq., and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, et seq.;

h. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, et seq., and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit, 5, §§ 205-A, et seq.;

i. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

j. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§ 445.771, et seq., and the Michigan Consumer Protection Act, §§ 445.901, et seq.;

k. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, et seq., and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, et seq.;

l. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, et seq., and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, et seq.;

m. New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Antitrust Act, NJ. Stat. Ann. §§ 56:9-1, et seq., and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, et seq.;

n. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, et seq., and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, et seq.;

o. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, et seq., and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, et seq.;

p. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, et seq.;

q. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, et seq., and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, et seq.;

r. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, et seq., and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, et seq.;

s. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, et seq., and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, et seq.;

t. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, et seq.;

u. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, et seq., and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, et seq.; and

v. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, et seq., and the Wisconsin Unfair Trade Practices Act, Wis. Stat. § 100.20, et seq.

119. As a result of the conduct described above, Plaintiff and the Class have sustained and will continue to sustain substantial losses to their businesses and their property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions

of Toprol-XL, and paying for metoprolol succinate at higher prices than they would have been but for Defendants' actions. The present amount of such damages is presently unknown but will be determined through discovery and presented at trial.

120. Plaintiff and the Class seek damages, multiple damages, treble damages, and other damages permitted by state law, for the injuries caused by Defendants' unlawful actions pursuant to the aforementioned state statutes.

COUNT III

FOR INJUNCTIVE AND DECLARATORY RELIEF UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

121. Plaintiff repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

122. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as proscribed practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, et seq., the Arizona Consumer Fraud Act, Ariz. Rev. Stat. §§ 44-1521, et seq., and the Constitution of the State of Arizona, Article 14, § 15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, et seq., and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, et seq.;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, et seq.;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, et seq., and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, et seq.;

e. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statues §§ 480-2, 480-3, and 480-4.

f. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, et seq.,and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, et seq.;

g. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§51:121, et seq., and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, et seq.;

h. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, et seq.;

i. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass, Gen. Laws ch. 93A;

j. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, et seq., and the Michigan Consumer Protection Act, §§ 445.901, et seq.;

k. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, et seq., and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, et seq.;

l. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, et seq., and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, et seq.;

m. New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann, §§ 56:9-1, et seq., and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, et seq.;

n. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, et seq., and the New Mexico Unfair Practices Act, N.M. Stat, Ann. §§ 57-12-1, et seq.;

o. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, et seq., and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, et seq.;

p. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, et seq.

q. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, et seq., and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, et seq.;

r. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, et seq., and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, et seq.;

s. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Term. Code Ann. §§ 47-25-101, et seq., and the Consumer Protection Act, Term. Code Ann. §§ 47-18-101, et seq.;

t. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat, Ann. tit. 9, §§ 2451, et seq.;

u. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, et seq., and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, et seq.; and

v. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, et seq., and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, et seq.

123. Plaintiff and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of Toprol-XL, and paying higher prices for metoprolol succinate and generic versions of Toprol-XL than they would have paid but for Defendants' improper actions. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

124. Plaintiff and the Class, pursuant to laws of the Indirect Purchaser States, hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through

the use of the invalid '161 and '154 patents is unlawful. Plaintiff and the Class further seek equitable and injunctive relief pursuant to the laws of the Indirect Purchaser States to correct for the anti-competitive market effects and other harms to purchasers caused by the unlawful conduct of Defendants, and other relief so as to assure that similar conduct does not occur in the future.

COUNT IV

FOR RESTITUTION, DISGORGEMENT AND IMPOSITION OF A CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

125. Plaintiff repeats and realleges all preceding paragraphs of this Complaint as if fully set forth herein.

126. Defendants have benefited from the supracompetitive and artificially inflated prices and monopoly profits on their sale of Toprol-XL resulting from their unlawful and inequitable acts alleged in this Complaint.

127. Defendants' financial benefits resulting from their unlawful and inequitable conduct resulted from and are economically traceable to overpayments for Toprol-XL by Plaintiff and members of the Class.

128. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

129. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Toprol-XL is a direct and proximate result of Defendants' unlawful practices.

130. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

131. It would be inequitable and unjust for Defendants to be permitted to retain any of the unlawful proceeds resulting from fraudulently, illegally or inequitably obtaining the patents, or illegally or wrongfully listing them in the Orange Book or from the commencement or maintenance of baseless patent infringement lawsuits.

132. It would be inequitable for the Defendants to be permitted to retain any of the overcharges for Toprol-XL derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

133. Defendants should be compelled to disgorge to a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds received by them.

134. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

135. Plaintiff and the Class and have no adequate remedy at law.

WHEREFORE, Plaintiff respectfully requests that this Court enter an Order:

A. certifying the Class (or subclasses) pursuant to the Federal Rules of Civil Procedure, certifying Plaintiffs as the representatives of the Class (or subclasses), and designating their counsel as counsel for the Class (or subclasses);

B. declaring the '398 Patent invalid, and declaring its listing in the Orange Book invalid and a violation of §2 of the Sherman Act.

C. declaring the '161 and '154 patents invalid, and declaring their listing in the Orange Book invalid and a violation of the antitrust and/or deceptive practices statutes in the Indirect Purchaser states;

D. declaring that Defendants' commencement and/or maintenance of patent infringement lawsuits against filers of ANDAs for Toprol-XL baseless and a violation of § 2 of the Sherman Act;

E. declaring the Defendants' commencement and/or maintenance of patent infringement lawsuits against filers of ANDAs for Toprol-XL baseless and a violation of the antitrust and/or deceptive practice statutes in the Indirect Purchaser States;

F. enjoining and restraining Defendants' continuing violations of § 2 of the Sherman Act, pursuant to § 16 of the Clayton Act;

G. granting Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

H. granting Plaintiffs and the Class damages or multiple damages as permitted by law;

I. granting Plaintiffs and the Class their costs of prosecuting this action, together with interest and reasonable attorneys' fees, experts' fees and costs; and

J. granting such other relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury of all issues so triable in this case.

PRICKETT, JONES & ELLIOTT, P.A.

By: _____

Gary F. Traynor (DE Bar I.D. No. 2131)
J. Clayton Athey (DE Bar I.D. No. 4378)
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Attorneys for Plaintiff

DATED: February 6, 2006

OF COUNSEL:

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Tel: 610-667-7706
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JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Gross, Mary Anne

(b) County of Residence of First Listed Plaintiff York Co., Penna.
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Gary F. Traynor (DE Bar I.D. # 2131)/J. Clayton Athey (DE Bar I.D.# 4378)
Prickett, Jones & Elliott, P.A., 1310 King St., PO Box 1328,
Wilmington, DE 19899-1328 (302) 888-6500

DEFENDANTS AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
15 U.S.C. 26

Brief description of cause: Class action complaint alleging violations of federal antitrust and state unfair and deceptive trade practices acts arising from the manufacturing and marketing of Toprol-XL.

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Sleet DOCKET NUMBER 06-CV-52, 63, 71, 73, 79

DATE 2/6/2006

SIGNATURE OF ATTORNEY OF RECORD

DE Bar I.D. #2131

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

06 81

Civil Action No. _____

ACKNOWLEDGMENT OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE TO EXERCISE JURISDICTION

I HEREBY ACKNOWLEDGE RECEIPT OF 3 COPIES OF AO FORM 85.

2/6/06
(Date forms issued)

(Signature of Party or their Representative)

David L. Gregory
(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action